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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P-0020	5717

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EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/010,304	<b>Applicant(s)</b> RINGEISEN, TIMOTHY	
	<b>Examiner</b> Eric E. Silverman, PhD	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6 - 14, 16 - 24, and 28 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 - 14, 16 - 24, and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Applicant is advised that the Examiner and Art Unit to which this Application is assigned have changed. The Art Unit to which this application is currently assigned is **Art Unit 1615**, and the Examiner to which this application is currently assigned is **Eric E. Silverman, PhD**, whose contact information can be found at the end of this action.

Receipt of Amendment, remarks and arguments attached thereto, filed 11/15/05, is acknowledged.

In amendment, Claims 1 – 5, 15 – 17, 25 – 27, and 29 – 32 were cancelled and the remaining claims were amended. Accordingly, claims 6 – 14, 16 – 24, and 28 are pending in this action.

### ***Claim Objections***

#### ***Response to Arguments***

The amendment filed 11/15/05 clarified the informalities that caused the objection to claims 13, and 14. Accordingly, these objections are withdrawn. The objection to claims 27 and 28 are moot since those claims have been cancelled.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 10, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn et al., US 5,077,049.

Dunn discloses a process for making a porous polymeric implant. The implant comprises biologically active agents such as growth hormones and others (col. 6, line 51 – col. 7, line 2). Combining a polymer solution with a coagulating solvent forms the porous implant. The polymer solution comprises a biocompatible polymer dissolved in a solvent. The polymer can be polyurethane, and the second solvent can be DMS or THF (col. 5, lines 7 – 51). The mixture is injected into the body where it takes on the shape of the implant site, after which the solvents permeate out of the polymeric body leaving pores.

***Claim Rejections - 35 USC § 103***

Claims 6, 7, 9, and 18 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Einstman et al. (US 3,492,154) in view of Helmus (US 5,447,724) and Le Noane (US 4,769,286).

Einstman teaches a process of making a porous polymeric sheet of polyurethane. The process comprises adding a second solvent to a polyurethane solution. The second solvent is a non-solvent, which gels the solution. Chloroform is taught to be the second non-solvent (Abstract, col. 5, col. 7, claim 1). Einstman also suggests that the polymer may be used in combination with biological and supporting materials (col. 1, lines 37 – 41).

Helmus discloses medical devices where a surface comprises porous polymeric composition holding a biologically active agent (Abstract). The device can be in the form of any implantable device, including sutures. The polymers can be those of instant claims (col. 2, lines 15 – 65).

La Noane teaches reinforcing materials, which may be fibers, beads, rings or others. The devices using these materials comprise the porous polymers of instant claims (Abstract, claims).

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Einstman regarding how to make porous polymers with the devices of Helmus and the support structure of Le Noane. Einstman explicitly suggests medical uses for the polymeric materials, and so it would be obvious to modify Einstman according to Helmus in order to make the suggested medical devices. It would also be obvious to modify add reinforcing members to these devices, according to Le Noane, in order to increase the mechanical stability of the devices. Accordingly, the artisan would have a reasonable expectation of success of performing a method of making an implantable device consisting of a porous polymer as taught by Einstman in the forms taught by Helmus and with reinforcing materials as taught by Le Noane. With regard to instant claims requiring a specific order of addition of the active agent, the Artisan would recognize that the order of addition of this agent is merely an optimization of the process, and would add the active agent at an appropriate time in order to achieve the best result. Since changing the order of addition of reagents in a chemical process is well within the purview of the artisan, the artisan would enjoy a reasonable expectation of success.

Claims 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn et al (US 5,077,049) in view of Reischl et al (US 3,553,008).

The teachings of Dunn are discussed above.

Dunn does not teach the use of THF to dissolve the polymer.

Reischl teaches that THF is well known as a solvent to dissolve polymers, such as polyurethane.

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use THF as a solvent to dissolve the polymer of Dunn, as taught by Reischl. The motivation is that Reischl teaches that THF is a good solvent for polyurethanes. Accordingly, the skilled artisan when seeking appropriate solvents to used as polymer-dissolving solvent in the process of Dunn, would be motivated to use THF, since Reischl teaches that THF is a good solvent for polyurethanes. As such, the artisan would enjoy a reasonable expectation of success at practicing a process of making a porous polymeric body by using THF as the dissolving solvent, as taught by Reischl, and DMS as the gelling solvent, as taught by Dunn.

### ***Conclusion***

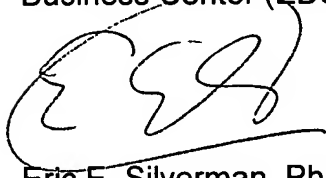
No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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